REMARKS

Claims 1-7, 9, 10, 12, 14 and 15 are pending. By this amendment, claims 1 and 2 are amended.

Amendments are solely to better define the claimed subject matter pursuant to discussions during a telephonic interview with the Examiner and her Supervisor on November 7, 2006. No new matter is added by the amendments. The amendments submitted after Final Office Action are for the purpose of presenting the rejected claims in better form for appeal. Applicants submit that the amendments do not raise new issues, do not require any further consideration or search by the Examiner and overcome all grounds of final rejection. Entry of the amendments are respectfully requested.

Reconsideration of the application is respectfully requested in view of the above amendments and the following remarks.

A. Substance of Interview with the Examiner

Applicants thank Examiner Nancy L. Zhang and SPE Ardin Marschel for the telephonic interview granted on November 7, 2006 with Applicants' representative Shantanu Basu, and Ted Kurtz and Harrihar Pershadsingh on behalf of the Applicant. An interview summary was mailed by the Examiner on November 15, 2006.

All pending claims were discussed in view of the outstanding rejections under 35 U.S.C. §§ 102(b) and 103(a) over Asmar reference. The Examiner and SPE asserted that the claims in the current form do not adequately define the claims to be directed at prevention of the claimed diseases in subjects not yet suffering from the disease conditions, as Applicants intend their claims to be read. The Examiners suggested amendments incorporating language directed to inhibition of "new onset" diseases and conditions. The Examiners agreed that submission of such amended claims in a supplemental amendment would be considered. An interview summary by the Examiner was mailed on November 15, 2006.

B. Amendments to the Claims

Claims 1 and 2 are amended in accordance with the claim language suggested by the Examiners.

Applicants amend claim 1 to specify a method for "decreasing an incidence of a new onset of type 2 diabetes mellitus, or treating an inflammatory or metabolic disorder selected from the group consisting of metabolic syndrome, and inflammation caused by osteoarthritis." (emphasis added).[1] Applicants note that the limitation of "treating an inflammatory or metabolic disorder selected from the group consisting of metabolic syndrome, and inflammation caused by osteoarthritis" was in the originally filed claims (e.g., originally filed claim 4).

Support for the amendments is found *inter alia* on paragraphs **0007, 0009, 0012** and **0128** of the specification. The concept of using compounds of the present invention to "lower incidence of new onset diabetes" is discussed interchangeably with the concepts of using these drugs to "decrease the risk for diabetes" and to "prevent diabetes." In paragraph **0012** the concept of "decreas[ing] the incidence of new onset type 2 diabetes" is discussed interchangeably with "preventing ... type 2 diabetes or other insulin resistance syndromes."

In paragraph **0009** of the Specification states that: "the prior art could not be used to predict that losartan, telmisartan, irbesartan, or any other ARB could be used to prevent or treat type 2 diabetes, the metabolic syndrome, or other forms of insulin resistance." This statement is in reference to the observations that "the *lower incidence of new-onset type 2 diabetes* in the losartan arm of the study actually reflected an increase in the incidence of new-onset type 2 diabetes in the atenolol arm" and "[s]tudies showing a *lower incidence of new onset diabetes* in patients treated with the ARB candesartan compared to patients treated with thiazide diuretics also indicate that the ARB candesartan did not decrease the risk for diabetes." (emphasis added).

In paragraph **0007**, the Specification interchangeably uses the concepts of using the drugs to "decrease the risk for diabetes" and to "prevent diabetes.":

[1] A corresponding amendment is made in claim 2, which depends from claim 1, in order to maintain antecedent basis for the claim language.

> It has been unclear whether ARBs actually decreased the risk for diabetes or whether the drugs to which they were being compared increased the risk for diabetes. For example, the lower risk of diabetes reported in patients given ARBs versus beta blockers or thiazide diuretics was due to the fact that beta blockers and thiazide diuretics aggravate insulin resistance and therefore, the results of clinical studies comparing ARBs to other agents cannot be used to predict whether ARBs can be used to prevent or treat diabetes or other disorders responsive to PPARgamma activators.

Specification, at paragraph **0007.**

Paragraphs **0056** and **0065** of the specification discuss the administration of telmisartan "to prevent, delay, slow, arrest or treat insulin resistance, pre-diabetes, glucose intolerance, impaired glucose tolerance ... ." These conditions are defined in paragraphs **0033, 0034, 0039** and **0040** of the specification to describe non-diabetic individuals who are "pre-disposed to the development of type 2 diabetes." This provides further support for the claim limitation of administering telmisartan to reduce the incidence of new onset type 2 diabetes.

Further, Example 5 at paragraph **0128** of the Specification, is a working example of administration of telmisartan to a patient with metabolic syndrome and at "risk of developing type II diabetes." Example 5 discloses administration of telmisartan for (i) *treating metabolic syndrome* and (ii) *preventing incidence of type 2 diabetes* which correspond to limitations of claim 1, as amended. The paragraph concludes that "[t]he telmisartan (Micardis®) therapy is continued according to the judgment of the clinician in order to prevent recurrence of the metabolic syndrome and *prevent development of type 2 diabetes*." (emphasis added).

Preventing type II diabetes as defined interchangeably with the concept of "decreas[ing] incidence of new onset diabetes" is described throughout the specification including, but not limited to, paragraphs **0013, 0014, 0016, 0017, 0019, 0023, 0056, 0065, and 0077**. No new matter is added by these amendments and their entry is respectfully requested.

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C. Claim rejections under 35 U.S.C. § 102(b)

Claims 1-7, 9, 11 and 12 stand rejected under 35 U.S.C. § 102(b) over Asmar *et al.* ("Asmar I") which is cited for teaching the treatment of type 2 diabetes and associated complications such as hypertension.

As discussed previously in the After Final response filed June 30, 2006 and in light of the current amendments to claims 1, 2, 4 and 7, Applicants submit that to prevent new onset of type 2 diabetes is not anticipated by Asmar as these limitations relate to administration of telmisartan to a population not (yet) suffering from type 2 diabetes and therefore are not inherently anticipated by Asmar which teaches administration of telmisartan to patients suffering from type II diabetes. Asmar does not teach or suggest the administration of telmisartan to a population not suffering from type 2 diabetes in order to decrease the incidence of new-onset diabetes type II.

No art has been cited that anticipate the claim limitation of "treating an inflammatory or metabolic disorder selected from the group consisting of metabolic syndrome, and inflammation caused by osteoarthritis" by administering a therapeutically effective amount of telmisartan.

Claims 2-7, 9, 11 and 12 depend from amended claim 1. In view of the amendments, Applicants respectfully request withdrawal of this ground for rejection under 35 U.S.C. § 102(b).

D. Claim rejections under 35 U.S.C. § 103(a)

Claims 10, 14 and 15 stand rejected under 35 U.S.C. § 103(a) over Asmar *et al.* which is cited for inherently teaching the treatment of type 2 diabetes and associated complications such as hypertension, and the topical administration and dosage limitations of claims 10, 14 and 15 being obvious modifications.

As discussed above, claim 1, as amended, is not (inherently) anticipated by Asmar. Claims 10, 14 and 15 depend from claim 1. Because all limitations of claims 10, 14 and 15 are not taught or suggested by Asmar, Applicants respectfully request withdrawal of this ground for rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 421842000400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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